

REMARKS

The Official Action of August 18, 2006, and the prior art applied therein have been carefully reviewed. The claims in the application are now claims 1-16, and these claims define patentable subject matter warranting their allowance. Accordingly, the applicants respectfully request favorable reconsideration and allowance.

Applicants note paragraph 12 in the Office Action Summary, but note that box 12a has not been checked. However, as there is only one priority application, applicant understands from the checking of box 12 and box 12-3 that the PTO is acknowledging receipt of applicants' papers filed under Section 119.

New claims 10-16 have been added. Claim 10 is based on original claims 1 and 6, along with portions of applicants' specification at page 4, line 16 and 22-23; page 5, lines 13-15; page 6, lines 2-8; page 7, lines 2-5; and Example 2, particularly in the top paragraph on page 6. Claims 11-15 dependent on new claim 10 are based on original claims 2-4. Claim 16 is also based on page 6 at line 7. The new claims are patentable for reasons set forth below in reply to the outstanding rejection.

Claims 1-9 have been rejected under Section 102 as anticipated by Greenwalt et al USP 6,056,970 ("Greenwalt"). This rejection is respectfully traversed.

In the first place, it should be noted that the material used for holding thrombin in accordance with the present invention is bioabsorbable synthetic **nonwoven** fabric. The present inventors have found that a bioabsorbable synthetic material processed in the form of a nonwoven fabric made of polyglycolic acid, polylactic acid, a copolymer of glycolic acid with lactic acid or the like, which holds thrombin as an effective ingredient, may advantageously be used in an improved way for a topical hemostatic material since it has an appropriate elasticity and flexibility to ensure valid sealing as well as excellent operability and easy handling when used for topical hemostatic. On the contrary, although Greenwalt discloses a bioabsorbable hemostatic composition comprising a bioabsorbable polymer such as polyglycolide and a hemostatic compound such as thrombin or fibrinogen, it does not teach the use of a material in the form of a nonwoven fabric, an elastic and flexible sealing member.

A reading of Greenwalt suggests that the Greenwalt product is mat-like or, at best, paper-like. There is no

indication that such a product has the flexibility and covering characteristics of applicants' product.

Second, applicants note that Greenwalt teaches the application of the bioabsorbable polymers in an **organic solvent**, i.e. a non-aqueous solvent which may be a toxic or unhealthy chemical, e.g. carbon tetrachloride is mentioned as one solvent example, and then drying (lyophilizing) the combination. On the contrary, a process for preparing a bioabsorbable synthetic nonwoven fabric holding thrombin in accordance with the present invention as called for in claims 6 and 10 do not involve the use of organic solvent, but instead thrombin is dissolved in an aqueous saline or buffer solution (see page 6, line 2).

Moreover, although the Greenwalt product is not exactly the same as the comparative product against which applicants' nonwoven has been tested (see especially Group 4 on page 9 applicants' specification), it does seem quite similar to such a hemostatic sponge. Noting Table 1 on page 11 of applicants' specification, it can be seen that the relatively thick Group 4 product gave very poor results compared with applicants' non-woven fabric.

Thus, the structure of applicants' device is important, as well as the components from which it is made. Moreover, the way it is made also affects the structure, and

therefore the features recited in claims 6 and 10-15 should not be overlooked.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-9 have also been provisionally rejected on the basis of non-statutory obviousness-type double patenting over certain of the claims of copending application 10/542,577. While this rejection is believed to be premature because there are no patented claims, and therefore there cannot be any real double patenting until there are patented claims, applicants wish to clear the record of this rejection, without admitting its validity.

Accordingly, filed herewith is a terminal disclaimer executed by undersigned attorney of record. As such terminal disclaimer has been executed by an attorney of record, compliance with 37 CFR 3.473(b) is unnecessary.

Withdrawal of the rejection is respectfully requested.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

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Amd. dated February 16, 2007
Reply to Office Action of August 18, 2006

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application. Favorable consideration and early formal allowance are respectfully requested.

Respectfully submitted,

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